

LFW 1615



PATENT
Attorney Docket No. 056291-5174-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **GELLERT *et al.***

Application No.: **10/505,231**

Filed: **August 19, 2004**

For: **PHARMACEUTICAL FORMULATION OF
IRESSA COMPRISING A WATER-SOLUBLE
CELLULOSE DERIVATIVE**

Group Art Unit: **1615**

Examiner: *Unassigned*

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants petition the Examiner to consider this Information Disclosure Statement and documents listed on the attached Form PTO-1449. To the best of the undersigned's knowledge, this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced Application. Accordingly, Applicants do not believe a fee is due for filing this Supplemental Information Disclosure Statement.

With the exception of U.S. Patents and Publications, copies of the listed documents are attached. Documents 1, 11, 24 and 28 were cited in an International Search Report which issued in a corresponding PCT application PCT/GB03/00803, a copy of which is attached for the Examiner's convenience. Applicants respectfully request that the Examiner initial and return the Form PTO-1449, indicating that the information has been considered and made of record herein.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior

art." If it should be determined that the listed documents constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such document.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

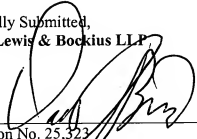
Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-0310. This paragraph is intended to be a

CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R.

§1.136(a)(3).

Respectfully Submitted,

Morgan Lewis & Bockius LLP



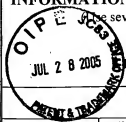
Date: July 28, 2005
Morgan Lewis & Bockius LLP
Customer No. **09629**
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
Tel. No.: 202-739-3000

By:

Registration No. 25,323
Tel. No.: (202) 739-5320
Fax No.: (202) 739-3001

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)



PTO Form 1449

Attorney Docket No.
056291-5174-US

Application No. 10/505,231

Applicants: GELLERT *et al.*

PAGE 1 of 2

Filing Date: August 19, 2004

Group Art Unit: 1615

U.S. PATENT DOCUMENTS

Initial	Document No.	Date	Name	Class	Sub-Class	Filing Date
	1. 2003/045537	March 6, 2003	Lee <i>et al.</i>			
	2. 2002/009494	January 24, 2002	Curatolo <i>et al.</i>			
	3. 6,383,471	May 7, 2002	Chen <i>et al.</i>			
	4. 6,294,192	September 25, 2001	Patel <i>et al.</i>			
	5. 6,248,771	June 19, 2001	Shenoy <i>et al.</i>			
	6. 5,631,248	May 20, 1997	Davis <i>et al.</i>			
	7. 5,616,582	April 1, 1997	Barker			
	8. 5,559,158	September 24, 1996	Al-Razzak <i>et al.</i>			
	9. 5,457,105	October 10, 1995	Barker			
	10. 4,704,284	November 3, 1987	Beatty <i>et al.</i>			
	11. 4,344,934	August 17, 1982	Martin <i>et al.</i>			

FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Sub-Class	Translation
12.	WO 03/32956	April 24, 2003	WIPO			
13.	WO 03/00294	January 3, 2003	WIPO			
14.	WO 02/89773	November 14, 2002	WIPO			
15.	WO 02/20020	March 14, 2002	WIPO			
16.	WO 02/02534	January 10, 2002	WIPO			
17.	WO 01/76586	October 18, 2001	WIPO			
18.	WO 01/47495	July 5, 2001	WIPO			
19.	WO 01/04102	January 18, 2001	WIPO			
20.	WO 00/59475	October 12, 2000	WIPO			
21.	WO 00/00179	January 6, 2000	WIPO			
22.	WO 98/38984	September 11, 1998	WIPO			
23.	WO 96/38131	December 5, 1996	WIPO			
24.	WO 96/33980	October 31, 1996	WIPO			
25.	EP 1027887	August 16, 2000	EPA			
26.	EP 1027886	August 16, 2000	EPA			
27.	EP 901786	March 17, 1999	EPA			
28.	GB 2,306,885	May 14, 1997	Great Britain			
29.	JP 09059159	March 4, 1997	Japan			Yes

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)

30.	Barker <i>et al.</i> "Studies leading to the identification of ZD1839 (IRESSA): an orally active, selective epidermal growth factor receptor tyrosine kinase inhibitor targeted to the treatment of cancer" <i>Bioorg Med Chem Lett.</i> 11(14): 1911-1914 (2001)
31.	Hasegawa <i>et al.</i> "Supersaturation mechanism of drugs from solid dispersions with enteric coating agents" <i>Chem Pharm Bull (Tokyo)</i> 36(12): 4941-4950 (1988)
32.	Herbst <i>et al.</i> "Selective oral epidermal growth factor receptor tyrosine kinase inhibitor ZD1839 is generally well-tolerated and has activity in non-small-cell lung cancer and other solid tumors: Results of a phase I trial" <i>J Clin Oncol</i> 20(18): 3815-3825 (2002)

Examiner _____ Date Considered _____

Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)		Attorney Docket No. 056291-5174-US		Application No. 10/505,231		
		Applicants: GELLERT <i>et al.</i>				PAGE 2 of 2
		Filing Date: August 19, 2004		Group Art Unit: 1615		
U.S. PATENT DOCUMENTS						
Initial	Document No.	Date	Name	Class	Sub-Class	Filing Date
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-Class	Translation
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, etc.)						
33.	Iervolino et al. "Membrane penetration enhancement of ibuprofen using supersaturation" Int. J. Pharm. 198: 229-238 (2000)					
33.	Iervolino et al. "Penetration enhancement of ibuprofen from supersaturated solutions through human skin" Int. J. Pharm. 212: 131-141 (2001)					
35.	Ikeda et al. Chem. Pharm. Bull., 42(11): 2320-2326 (1994)					
36.	Lawrence et al. "Small-molecule tyrosine kinase inhibitors as radiosensitizers" Seminars in Radiation Oncology 12(3): 33-36 (2002)					
37.	Lofsson et al. "The effect of water-soluble polymers on aqueous solubility of drugs" Int. J. Pharm. 127: 293-296 (1996)					
36.	Magne et al. "New cytotoxic and molecular-targeted therapies of head and neck tumors" Current Opinion in Oncology 16(3): 225-230 (2004)					
39.	Megrab et al. "Oestradiol permeation through human skin and silastic membrane: effects of propylene glycol and supersaturation" J. Control Rel 36: 277-294 (1995)					
40.	Moser et al. "Stabilization of supersaturated solutions of a lipophilic drug for dermal delivery" Int. J. Pharm. 224: 169-176 (2001)					
41.	Pellett et al. "The penetration of supersaturated solutions of piroxicam across silicone membranes and human skin in vitro" J. Control Release 46: 205-214 (1997)					
42.	Raghavan et al. "Effect of cellulose polymers on supersaturation and in vitro membrane transport of hydrocortisone acetate" Int. J. Pharm. 193(2): 231-237 (2000)					
43.	Ranson et al. "ZD1839, a Selective Oral Epidermal Growth Factor Receptor-Tyrosine Kinase Inhibitor, Is Well Tolerated and Active in Patients With Solid, Malignant Tumors: Results of a Phase I Trial" Journal of Clinical Oncology 20(9): 2240-2250 (2002)					
44.	Usui et al. "Inhibitory Effects of Water-Soluble Polymers on Precipitation of RS-8359" Int. J. Pharm. 154: 59-66 (1997)					
45.	Wakeling et al. "An Orally Active Inhibitor of Epidermal Growth Factor Signaling with Potential for Cancer Therapy" Cancer Research 62: 5749-5754 (2002)					
Examiner		Date Considered				
Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.						